IUCLID

Data Set

Existing Chemical	:	ID: 68515-75-3
EINECS Name	:	Hexanedioic acid, di-C7-9-branched and linear alkyl esters
Generic name	:	Di(C7-9-alkyl) adipate
CAS No.	:	68515-75-3
EINECS No.	:	271-105-9
Tag name	:	97 Adipate

Producer Related Part

Company	:	Solutia Inc.
Creation date	:	30.04.2001

Substance Related Part

Company	:	Solutia Inc.
Creation date	:	30.04.2001
Memo	:	
Printing date	:	18.11.2002
Revision date	:	30.04.2001
Date of last Update	:	18.11.2002
Number of Pages	:	19
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 OECD AND COMPANY INFORMATION

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2.1 MELTING POINT

2.2 BOILING POINT

Value	:	224 deg. C.
Decomposition	:	
Method		other
Year	:	1982
GLP	:	no data
Test substance	:	other TS
Result	:	
Test substance	:	97 Adipate technical grade with purity of 99%.
Reliability	:	(2) valid with restrictions Solutia in-house study
Flag	:	Critical study for SIDS endpoint

18.11.2002 (3)

2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value	:	13 hPa at 224° C
Decomposition	:	
Method		other (measured)
Year	:	1982
GLP	:	no data
Test substance	:	other TS
Result	:	Other values: 4.4 hPa @ 200 degrees C; 36 hPA @ 250 degrees C.
Test substance	:	97 Adipate technical grade with purity of 99%.
Reliability	:	(2) valid with restrictions Data consistent with other values measured at temperatures above and below the temp. used in this study
Flag	:	Critical study for SIDS endpoint

18.11.2002 (3)

2.5 PARTITION COEFFICIENT

Log pow	:	> 6.48 at ° C
Method		other (measured)
Year	:	1980
GLP	:	no data
Test substance	:	other TS
Method	:	Used purified octanol (extracted 2X with H2SO4 and NaOH) and twice distilled deionized water. Four concentrations (110, 150, 1100 and 1200 ppm) of 97 Adipate in octanol were evaluated. The amount of 97 Adipate remaining in the octanol was determined by diluting the octanol with isooctane containing methyl stearate internal standard followed by GC/MS analysis. Level of detection was 5 ppb.
Result	:	After centrifuging the water to completely separate the phases, the average

concentration in all the waters was less than the lowest level of detection (< 5 ppb). Using this level a calculated lower limit for P was determined as >2.2 X 10E5 and a corresponding BCF calculated to be > 1000 using the method of Neely et al 1974. Environ Sci Technol 8:1113.

Test substance : Technical grade 97 Adipate is 99%.
Reliability : (2) valid with restrictions
Method consistent with OECD guidance and well documented.
Flag : Critical study for SIDS endpoint
18.11.2002 (11)

2.6.1 WATER SOLUBILITY

Value : < .048 mg/l at 25 ° C
Qualitative :
Pka : at 25 ° C
PH : at and ° C
Method : other
Year : 1982
GLP : yes
Test substance : other TS
Method : Saturator column technique used. A level of 5% 97 Adipate was coated on a 100 mesh Chromosorb WHP column, then loaded into a saturator column. Vials of eluent were collected, each containing isooctane with methyl stearate as an internal standard. Four vials were taken during a flow rate of 5 ml/m and 4 at a flow rate of 2.5 ml/m. 97 Adipate was measured by GC/MS using a level of 48 ppb as the limit of detection.
Result : A total of 8 samples were taken and analyzed, with no detectable 97 Adipate found in any sample. Hence, the water solubility was considered less than 48 ppb, the limit of detection in this assay.
Test substance : Technical grade is 99% pure.
Reliability : (2) valid with restrictions
Method consistent with OECD guidance and well documented.
Flag : Critical study for SIDS endpoint
24.10.2002 (13)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	:	water
Light source	:	Sun light
Light spect.	:	nm
Rel. intensity	:	based on Intensity of Sunlight
Direct photolysis		
Halflife t1/2	:	
Degradation	:	0 % after 14 day
Quantum yield	:	
Deg. Product	:	
Method	:	other (measured)
Year	:	1981
GLP	:	yes
Test substance	:	other TS
Method	:	Used sunlight photolysis screening method following ASTM E47.06 guidance, whereby 97 Adipate was added to quartz tubes containing either purified water or membrane-filtered river water and held either in darkness or in a combination of sunlight (14 hr) and darkness (10 hr), 24 hr/day for up to 14 days. A 0.107 g/100 ml 97 Adipate stock solution was made in acetonitrile; then 100 ul of a 10:100 ml dilution was injected into quartz tubes containing 10 ml of either membrane-filtered, purified water or membrane-filtered river water. A total of 20 tubes were prepared, with 4 tubes analyzed at time 0, and two tubes containing each type of water with test material that were analyzed after 2, 5, 9 and 14 days of testing. The ave. low temp. during this study was 64 degrees F. and the high ave. was 81 degrees F. Each test vial was extracted with isooctane and analyzed for test material by GC/MS. Due to initial results obtained, a stability experiment was also conducted in a similar pattern as before, except triplicate tubes were extracted immediately after spiking, after refrigeration and after sterilization with formaldehyde.
Result	:	Initial studies indicated rapid loss in both samples, those exposed to sunlight as well as those exposed to complete darkness; the T1/2 of samples exposed to darkness were equal to or less than those exposed to sunlight. These data suggested that phenomenon other than direct photolysis or chemical transformation was occurring. For this reason the stability study was conducted. Results of the stability study confirmed that no detectable photolytic or chemical transformation occurs after the addition of 97 Adipate and the loss observed in the initial studies were the result of biodegradation from contamination of bacteria in the test system.
Test substance	:	Technical grade is 99% pure.
Reliability	:	(2) valid with restrictions In-house study with good documentation.
Flag	:	Critical study for SIDS endpoint

24.10.2002 (12)

3.1.2 STABILITY IN WATER

Deg. Product	:	
Method	:	other (calculated)
Year	:	2002
GLP	:	no
Test substance	:	no data
Method	:	Calculated estimates from HYDROWIN, ver. 1.67.
Result	:	Half-life estimated to be 3.215 yr. Hydrolysis is slow at neutral pH and breaks down to mono ester and free alcohol.
Reliability	:	(2) valid with restrictions

Model used to estimate hydrolysis is recommended by US EPA for this purpose.

Flag : Critical study for SIDS endpoint
24.10.2002 (1)

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : fugacity model level III
Media :
Air (level I) : .278
Water (level I) : 3.61
Soil (level I) : 27.3
Biota (level II / III) :
Soil (level II / III) : 68.8
Method : other
Year : 2002
Method : Calculated using estimated values according to Mackay, Level III. Assumed emissions (1000 kg/hr) to air, water and soil compartments using following data inputs: Henry's LC=1.81e-005 atm-m3/mole (Henrywin program), Vapor Press=6.67e-005 mm Hg (Mpbpwin program), Liquid VP=7.46e-005 mm Hg (super-cooled), Melting Pt=29.9 deg C (Kowwin program) and Soil Koc=1.45e+007 (calc by model). Last soil entry included data estimate for sediments.

Results

```
Level III Fugacity Model (Full-Output):
=======================================
  Chem Name   : Hexanedioic acid, di-C7-9-branched and linear
alkyl esters
  Molecular Wt: 356.55
  Henry's LC  : 1.81e-005 atm-m3/mole (Henrywin program)
  Vapor Press : 6.67e-005 mm Hg  (Mpbpwin program)
  Liquid VP   : 7.46e-005 mm Hg  (super-cooled)
  Melting Pt  : 29.9 deg C (Mpbpwin program)
  Log Kow     : 7.55  (Kowwin program)
  Soil Koc    : 1.45e+007  (calc by model)

          Concentration   Half-Life    Emissions
            (percent)        (hr)       (kg/hr)
   Air        0.278          10.8         1000
   Water      3.61           900          1000
   Soil       27.3           900          1000
   Sediment   68.8           3.6e+003     0

              Fugacity    Reaction    Advection   Reaction
Advection
               (atm)      (kg/hr)      (kg/hr)    (percent)
(percent)
   Air       9.01e-012    855         133          28.5
4.44
   Water     1.78e-012    133         173          4.43
5.76
   Soil      1.06e-014    1.01e+003   0            33.5
0
   Sediment  1.20e-012    634         65.9         21.1
2.2

   Persistence Time: 1.6e+003 hr
   Reaction Time:    1.82e+003 hr
```

```
Advection Time:   1.29e+004 hr
Percent Reacted:  87.6
Percent Advected: 12.4

Half-Lives (hr), (based upon Biowin (Ultimate)and Aopwin):
   Air:      10.78
   Water:    900
   Soil:     900
   Sediment: 3600
     Biowin estimate: 2.692  (weeks-months)

Advection Times (hr):
   Air:      100
   Water:    1000
   Sediment: 5e+004
```

Reliability : (2) valid with restrictions
Estimated values based on model recommended by US EPA.
Flag : Critical study for SIDS endpoint
24.10.2002 (1)

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type : aerobic
Inoculum :
Contact time :
Degradation : 67 - 88 % after 24 hour(s)
Result : readily biodegradable
Deg. Product :
Method : OECD Guide-line 302 A "Inherent Biodegradability: Modified SCAS Test"
Year : 1976
GLP : no
Test substance : other TS
Method : Two different measures of biodegradability were determined; 1) primary biodegradability measuring the disappearance of the analytical response for the original material was determined using the Semi-Continuous Activated Sludge (SCAS) technique, and 2) ultimate biodegradability, or conversion of the material to carbon dioxide, water, inorganic salts and normal metabolic products, was determined by carbon dioxide evolution procedures. The SCAS methodology followed that reported in J. Am Oil Chem Soc 46:432-440, a methodology consistent, but a predecessor of OECD test guideline 302. Test material was added to activated sludge obtained from a local domestic sewage treatment plant in 1.5 L glass vessels which were stirred magnetically at a level of 5 and 20 mg/24 hr. After a 3 week acclimation period, primary degradation was determined each week by analyzing 50-ml liquor samples withdrawn after feeding and at the end of the aeration cycle. Analysis was made using a GC with a FID detector. A blank unit was maintained on synthetic sewage without the addition of any test material. The Carbon dioxide Evolution test followed the procedures as outlined by Sturm (J. AM Oil Chem. Soc. 50:159-167, using both a T-D-S and Shake Flask system. The inoculum was prepared from a 14-day die away test.
Result : Primary biodegradation was determined to be 67+/- 14 % at the charge rate of 5 mg/24 hr of 97 Adipate and 88+/-5% at a rate of 20 mg/24 hr. ; CO2 evolution in the Ultimate biodegradation study was 90.2% and 78.7-

CO2 evolution in the Ultimate biodegradation study was 90.2% and 78.7-82.1% in the T-D-S and Shake flask methods tested, respectively.

Test substance : Technical grade 97 Adipate with purity of 99%.

Conclusion : Rapid and essentially complete degradation was observed in both the SCAS and CO2 Evolution tests, indicating rapid degradation by microbial populations in the environment.

Reliability : (1) valid without restriction
OECD Methodology, well documented.

Flag : Critical study for SIDS endpoint

18.11.2002 (2)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	static
Species	:	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
NOEC	:	> 1000
LC0	:	> 1000
Method	:	other
Year	:	1980
GLP	:	yes
Test substance	:	other TS
Method	:	Followed methods described in EPA-600/3-75-009, Methods for Acute Toxicity tests with Fish, Macroinvertebrates and Amphibians, 1975. The test treatments were prepared by individually mixing the appropriate amount of test substance with 10 ml of actone and adding it directly to the test chambers. The control also received 10 ml of acetone. One replicate was prepared for each test treatment and control. The test was performed in 5-gallon glass vessels containing 15 L of dilution water. The dilution water was filtered well-water. each treatment vessel contained 10 fish. Fish were obtained from Fenders' Fish Hatchery in Baltic, Ohio and had a mean lenth of 33 mm and weight of 0.43 g. Well water hardness was 225 ppm CaCo3.
Result	:	No mortalities were observed in any of the test concentrations tested, including: control, 100, 180, 320, 560 or 1000 mg/L. thus the LC50 is considered to be > 1000 mg/L. It should be recognized that the test substance was insoluble at all test levels as an oily sheen was seen in each treated vessel. Test temp. was 12+/-1 Deg C.; the pH range was 7.7-7.9 and Dissolved oxygen ranged from 8.6 -10 mg/L.
Test substance	:	Technical grade with purity of 99%.
Reliability	:	(2) valid with restrictions Study conducted according to well accepted test guidelines which preceeded OECD guidance and was well documented. Established that level of toxicity was above solubility limit (48ppb) of this test agent, although value cited for LC50 is far in excess.
Flag	:	Critical study for SIDS endpoint

09.10.2002 (5)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type	:	static
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
EC50	:	= 1.9
Method	:	other
Year	:	1980
GLP	:	yes
Test substance	:	other TS
Method	:	Followed methods outlined in USEPA, 660/3 -75-009. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. 1975. Test treatments were prepared by adding the test substance with 0.2 ml acetone directly to the test treatments. Two replicates of 10 organisms were tested per treatment. Test vessels were 250 ml beakers with 200 ml of test solution. The dilution water was well water. A moving average angle, Probit or Bionomial method was used for statistical analysis.

or Bionomial method was used for statistical analysis.

Result : An LC50 of 1.9 mg/L with CI of 1.5-2.3 mg/L. Mortality (%) observed at following levels: Control (0%), solvent control (0%), 1 mg/L (0%), 1.8 mg/L (55%), 3.2 mg/L (95%), 5.6 mg/L (85%), 10 mg/L (100%), 18 mg/L (100%). Test substance was observed on the surface of all treatment test vessels. Daphnids were observed trapped in the test substance, which affected immobilization.Test temp. was 20 +/-1 Deg. C., the pH was 7.4 during the study and the Dissolved oxygen was 9.2 mg/L. Water hardness was reported as 225 ppn CaCO3. Daphnia were < 24 hr old and obtained from in-house stock. Lighting was 16 hrs light and 8 hrs dark.

Test substance : Technical grade material with purity of 99%..

Conclusion : LC50 value above the level of solubility (i.e. < 1mg/L) is unreliable in this test due to test material interference and immobilization of test organisms above 1 mg/L. However, at a test level slightly above the determined level of solubility (1 mg/L) no deaths occurred and thus no interference with test material affected test results. Thus, this study is adequate to judge the lack of toxicity of this test agent at the level of water solubility.

Reliability : (2) valid with restrictions This study provides adequate information at the level of water solubility, where no toxicity was observed, in a well documented study conducted according to EPA test guidelines established prior to OECD codification of similar guidance.

Flag : Critical study for SIDS endpoint

09.10.2002 (6)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species : Selenastrum capricornutum (Algae)

Endpoint : growth rate

Exposure period : 96 hour(s)

Unit : mg/l

Analytical monitoring : no

EC50 : = 2.5

Method : other

Year : 1980

GLP : yes

Test substance : other TS

Method : Followed US EPA Printz Algal Assay Test (1978). A primary stock was prepared by adding the test substance to dimethylformamide (DMF). Secondary stock solutions (test treatments) were then prepared by serial dilution using the primary stock. A solvent control (0.05 ml, max. amount added to any test flask) of DMF was also tested. Algal growth medium was used as the control. Three replicates of each test treatment were tested. The initial algal concentration was 2.0X10E4 cells per ml.Lighting was = 4000 lux; temp. was 24+/-1 Deg. C; the pH range was 7.1-7.2. Algal culture stock was obtained from USEPA Environmental Research Laboratory, Corvallis, Oregon. Statistical methods used: probit, linear regression, Student's t-test for growth differences.Chlorophyll was measured daily using a Turner filter fluorometer. Cell counts were performed via a hemacytometer at study termination.

Result : EC50 (based on cell nos.) = 2.5 ppm; EC50 (based on chlorophyll measurements) = 1.8 ppm; Differences (between test level and control level) seen at 96 h in Chlorophyll: solvent control (0%), 0.3 mg/L (+17%), 0.6 mg/L (-13%), 1.2 mg/L (-56%), 2.5 mg/L (-61%), and 5 mg/L (-70%). Differences in cell no. at similar levels were: solvent control (-1%), 0.3 mg/L (+4%), 0.6 mg/L (-7%), 1.2 mg/L (-47%), 2.5 mg/L (-54%), and 5 mg/L (-62%).

Test substance : Technical grade test material was 99% pure.

Reliability : (2) valid with restrictions
Provides adequate toxicity information (NOEL < 48 ppb) up to the level of solubility, although EC50 is reportedly higher than the solubility limit.

Flag : Critical study for SIDS endpoint
27.09.2002 (8)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals	:	10
Vehicle	:	other
Value	:	> 15800 mg/kg bw
Method	:	other
Year	:	1970
GLP	:	no
Test substance	:	other TS
Method	:	Undiluted test material was fed by stomach tube to rats in increasing doses at increments of fractional log intervals. The dose levels were 2000, 3160, 5010, 7940, 12600 and 15800 mg/kg. Single rats were used for the lower doses while 5 rats (3 male, 2 female) were used at 15800 mg/kg. Daily observations were made for toxic signs and a complete necopsy was performed after 7 days.
Result	:	No animals died at any dose level. Toxic signs reported as reduced appetite and activity for 1-4 days and slight weakness. All rats were considered normal after 7 days. At necropsy, 2/5 rats at 15800 mg/kg were observed with slight congestion of the lungs.
Test substance	:	>99% pure
Conclusion	:	Compound considered practically non-toxic by oral ingestion in male and female rats.
Reliability	:	(2) valid with restrictions Conducted pre-GLP, but adequately documented.
Flag	:	Critical study for SIDS endpoint

03.09.2002 (14)

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LD0
Species	:	rabbit
Strain	:	New Zealand white
Sex	:	male/female
Number of animals	:	5
Vehicle	:	other
Value	:	> 7940 mg/kg bw
Method	:	other
Year	:	1970
GLP	:	no
Test substance	:	other TS
Method	:	Undiluted compound was applied in increasing doses at increments of 0.2 fractional log intervals to closely clipped, intact skin of male and female rabbits. Single animals were tested at lower dosages while 1 male and 1 female rabbit were tested at the highest level. The dose levels were 2000, 3160, 5010 and 7940 mg/kg. Treated areas were covered with plastic strips (occluded) and animals held in wooden stocks for 24 hrs before removal. Animals were observed for signs of toxicity for 14 days, after which they were necropsied and evaluated for macroscopic lesions.
Result	:	No deaths were observed in the study. Toxic signs reported were reduced appetite and activity, slight lethargy (2-5 days duration) and slight tremors (1-2 days) at 5010 and 7940 mg/kg. At necropsy, rabbits at 5010 and

(1-2 days) at 5010 and 7940 mg/kg. At necropsy, rabbits at 5010 and 7940 mg/kg were observed with slight congestion of the lungs and areas of slight discoloration of the liver.

Test substance	:	> 99% pure
Conclusion	:	Compound was considered practically non-toxic by dermal exposure in male and female rabbits.
Reliability	:	(2) valid with restrictions Pre-GLP study; provided as Supplemental information.

18.11.2002 (14)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Species	:	rat
Sex	:	male/female
Strain	:	Sprague-Dawley
Route of admin.	:	oral feed
Exposure period	:	90 days
Frequency of treatment	:	Daily
Post obs. period	:	None
Doses	:	0 (negative control), 0.1, 0.5 and 2.5 %;
Control group	:	yes, concurrent no treatment
NOAEL	:	> 2.5 %
Method	:	other
Year	:	1972
GLP	:	no
Test substance	:	other TS
Method	:	Methodology consistent with OECD 408 but preceeded codification. Groups of 15 male and 15 female rats were administered diets containing test substance at 0, 0.1, 0.5 or 2.5% for 13 weeks. The high dose male rats received approx. 1300 mg/kg/d and females received 1800 mg/kg/d. A comparative group of 15 rats/sex were given 2.5% dioctyl adipate. Body weights (15/sex/group) and food consumption (5/sex/group) were measured weekly. Individual animal observations were recorded daily and detailed exams performed weekly. No ophthalmoscopic exam was performed. Hematology (Hgb, Hct, RBC, Total and differential leukocytes), clinical blood chemistry (SAP, BUN, SGPT, fasting blood glucose) and urine analysis (Glu, Alb, pH, specific gravity, microscopic elements) were performed on 10 rats/sex/group from the untreated control group, the high dose test group and the DOA test group after 45 and 84 days on test. Absolute and relative organ weights were recorded for liver, kidney, spleen, gonads, heart and brain at study term ination. After 90 days, each rat was necropsied. A complete set of approx. 40 tissues was examined from 10 rats/sex from the untreated control group, the high dose test group, and the DOA group. Mean body weight, food consumption and organ weight values were evaluated by analysis of variance (ANOVA) and significant differences among the groups were examined by t-test. A level of $p<0.05$

differences among the groups were examined by t-test. A level of p<0.05 was used to determine significance.

Result : Three deaths occurred during the study and were attributed to an acute respiratory infection. There were no differences noted between the untreated control and any of the Di (C7-C9 alkyl) adipate test groups for body weights, food consumption, or blood or urine parameters. Small but significantly Increased absolute and relative kidney weights were noted for females, but not males, in the high dose group. These findings were not considered treatment-related based on the small changes seen only in females without corresponding clinical or microscopic parameters which would be indicative of a renal effect. Necropsy findings were considered spontaneous and not test substance-related. The most frequent findings in all groups were lesions in the trachea and lungs consistent with chronic infection. No weight changes nor microscopic findings indicative of a treat-related effect were observed in gonads from either sex. Dioctyl adipate (DOA) exhibited statistically significantly decreased body weight gains (both sexes) and statistically increased female kidney and liver weights and weight ratios.

Test substance : > 99% pure

Reliability : (2) valid with restrictions
Study underwent independent audit and judged to have met Acceptable standard by FDA. Individual data not presented in report.

Flag : Critical study for SIDS endpoint

18.11.2002 (9)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Ames test

System of testing : S. typhimurium strains TA98, TA100, TA1535 and TA1537

Concentration : 0.0, 0.01, 0.04, 0.2, 1.0, 3.0, and 10.0 uL/plate and 25 uL/spot in spot test

Cycotoxic conc. : none observed at highest dose tested of 10 uL/plate in plate incorporation assay

Metabolic activation : with and without

Result : negative

Method : OECD Guide-line 471 "Genetic Toxicology: Salmonella thyphimurium Reverse Mutation Assay"

Year : 1981

GLP : yes

Test substance : other TS

Method : Positive control chemicals were sodium nitrite, benzo(a)pyrene, 2-nitrofluorene, 9-aminoacridine and 2-aminoanthracene; the solvent control was ethanol. Concurrent solvent and positive controls were included in all experiments and performed as expected. A toxicity pretest with TA 100 was conducted with and without microsomal activation to determine cytotoxicity and identify the highest dose level to be used in the full study. Both plate incorporation and spot tests were conducted in triplicate in all strains with and without activation. A mutagenic response was defined as a reproducible, dose-related increase in the number of histidine-independent colonies over the spontaneous incidence. Bartlett's test was run to determine whether significant differences existed among treatment variables. Treatment groups were compared to solvent control using a 1-sided t-test and within level pooled variance. Dose response was further evaluated for all treatment groups found to be significantly (p<0.01) higher than solvent control.

Result : The substance was not mutagenic at doses up to 10 uL/plate in Salmonella strains TA 98, TA 100, TA 1535 and TA 1537 in the plate incorporation assay nor at 25 uL/spot in the spot test with or without metabolic activation. No microbial toxicity was observed in strain TA100 at concentrations up to 10 uL/plate in plate incorporation assay nor at 25 uL/spot in the spot test with or without metabolic activation. Decreased solubility was observed at 3

and 10 uL in the plate incorporation assay.

Test substance	:	> 99% pure
Conclusion	:	The test substance was not mutagenic in all strains tested.
Reliability	:	(1) valid without restriction
Flag	:	Critical study for SIDS endpoint

03.09.2002 (10)

5.6 GENETIC TOXICITY 'IN VITRO'

5.7 CARCINOGENITY

5.8 TOXICITY TO REPRODUCTION

5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rat
Sex	:	female
Strain	:	Sprague-Dawley
Route of admin.	:	gavage
Exposure period	:	Gestation days 6-19
Frequency of treatment	:	Daily during the gestation period
Duration of test	:	Animals were sacrificed on gestation day 20
Doses	:	0, 1000, 4000 and 7000 mg/kg/d
Control group	:	yes, concurrent vehicle
NOAEL Maternalt.	:	>= 4000 mg/kg bw
NOAEL Teratogen	:	>= 7000 mg/kg bw
NOAEL Embryotoxicity	:	>= 4000 mg/kg bw
NOAEL Fetotoxicity	:	>= 4000 - mg/kg bw
Method	:	OECD Guide-line 414 "Teratogenicity"
Year	:	1981
GLP	:	yes
Test substance	:	other TS
Method	:	Females were cohabited overnight with males in a 2:1 ratio. Gestation day 0 was determined the morning that vaginal sperm or plug was found. Mated females were assigned to groups to achieve 24/group. Female rats were dosed daily on Days 6-19 of gestation. Body weights were recorded on GD 0, 6, 15 and 20. Individual clinical observations were recorded on GD 0, 6, 10, 15 and 20. Animals were sacrificed on GD 20 and intact uteri were removed and weighed. All fetuses were weighed and examined for external abnormalities; approximately one half were processed for skeletal examination and one half preserved for soft tissue examination. Mean data was analyzed using analysis of variance (ANOVA). Bartlett's test was used to test for equal variance and Dunnett's test for differences from control For incidence data, a Chi-square analysis and Fisher's Exact Probability test were used, followed by Armitage's test for linear trend, if needed.
Result	:	No dams died during the study. Significant maternal body weight decreases ($p<0.01$) were observed at 7000 mg/kg/d. There were no significant differences in the number of implantations, live fetuses, resorptions or corpea lutea. There were no statistically significant effects on mean fetal body weight or sex ratio. High dose (7000 mg/kg) male and female fetal weights were slightly, but not statistically, reduced from the control, low and mid dose groups. There were no differences among groups for fetal ossification variations, external, visceral or skeletal malformations. A higher incidence of rudimentary structures was observed in high dose fetuses when compared to controls, but were within the range

in high dose fetuses when compared to controls, but were within the range of historical controls at this laboratory.

Test substance : > 99% pure
Conclusion : No evidence of developmental toxicity was observed at dose levels of 1000 and 4000 mg/kg/day. Maternal toxicity (reduced body weight) and embryotoxicity (reduced fetal weight) was observed at the highest dose (7000 mg/kd/d) tested.
Reliability : (1) valid without restriction
Flag : Critical study for SIDS endpoint
27.09.2002 (7)

5.10 OTHER RELEVANT INFORMATION

5.11 EXPERIENCE WITH HUMAN EXPOSURE

(1) EPIWIN, version 3.10. 2002. Syracuse Research Corp., Syracuse, NY.

(2) Saeger, VW, RG Kaley II, O Hicks, ES Tucker and JP Mieure. 1976. Appl Environ Microbiol. 31 (5):746-749.

(3) Solutia in-house study and cited on MSDS, 2002

(5) Solutia Study no. AB19800352. Acute toxicity of S-97A to Rainbow Trout.

(6) Solutia Study no. AB19800354. Acute toxicity of Santicizer 97A to Daphnia magna.

(7) Solutia Study no. BD-81-131. Teratogenicity study in rats with Santicizer 97.

(8) Solutia Study no. BN19800355. Toxicity of Santicizer 97A to the freshwater algae Selenstrum capricornatum.

(9) Solutia study no. BT-71-38. 90-Day subacute oral toxicity study with Santicizer 97 in albino rats.

(10) Solutia Study no. DA-80-503.Salmonella Mutagenicity Assay of Santicizer 97.

(11) Solutia study no. ES-80-SS-41. Octanol/Water Partition Coefficient of SANTICIZER 97A and Dioctyl Adipate.

(12) Solutia Study no. MO19820071.Sunlight photolysis screening of Santicizer 97.

(13) Solutia study no. MO20020442. Aqueous solubility of Santicizer 97.

(14) Solutia Study no. Y-70-112; Acute Toxicological Investigation of Santicizer 97A [EPA Document no. 88-920007905]

7.1 END POINT SUMMARY

7.2 HAZARD SUMMARY

7.3 RISK ASSESSMENT

I U C L I D

Data Set

Existing Chemical	:	ID: 110-33-8
CAS No.	:	110-33-8
EINECS Name	:	Di(n-Hexyl) Adipate
Generic name	:	DHA

Producer Related Part

Company	:	Solutia Inc.
Creation date	:	05.09.2002

Substance Related Part

Company	:	Solutia Inc.
Creation date	:	05.09.2002
Memo	:	
Printing date	:	25.10.2002
Revision date	:	
Date of last Update	:	06.09.2002
Number of Pages	:	11
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 OECD AND COMPANY INFORMATION

1.0.2 LOCATION OF PRODUCTION SITE

1.0.3 IDENTITY OF RECIPIENTS

1.1 GENERAL SUBSTANCE INFORMATION

1.1.0 DETAILS ON TEMPLATE

1.1.1 SPECTRA

1.2 SYNONYMS

1.3 IMPURITIES

1.4 ADDITIVES

1.5 QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.7 USE PATTERN

1.7.1 TECHNOLOGY PRODUCTION/USE

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.9 SOURCE OF EXPOSURE

1.10.1 RECOMMENDATIONS/PRECAUTIONARY MEASURES

1.10.2 EMERGENCY MEASURES

1.11 PACKAGING

1.12 POSSIB. OF RENDERING SUBST. HARMLESS

1.13 STATEMENTS CONCERNING WASTE

1.14.1 WATER POLLUTION

1.14.2 MAJOR ACCIDENT HAZARDS

1.14.3 AIR POLLUTION

1.15 ADDITIONAL REMARKS

1.16 LAST LITERATURE SEARCH

1.17 REVIEWS

1.18 LISTINGS E.G. CHEMICAL INVENTORIES

2.1 MELTING POINT

2.2 BOILING POINT

2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

2.5 PARTITION COEFFICIENT

2.6.1 WATER SOLUBILITY

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

3.1.2 STABILITY IN WATER

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.1.1 ACUTE ORAL TOXICITY

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test
System of testing	:	TA1535, TA1537, TA1538, TA98, & TA100
Concentration	:	0, 167, 500, 1,670, 5,000, 7,500 and 10,000 ug/plate
Cycotoxic conc.	:	> 10,000 ug/plate
Metabolic activation	:	with and without
Result	:	negative
Method	:	OECD Guide-line 471 "Genetic Toxicology: Salmonella thyphimurium Reverse Mutation Assay"
Year	:	1992
GLP	:	yes
Test substance	:	other TS
Method	:	Presceening study conducted with TA1538 and TA100 to determine toxicity at 15, 167, 500, 1670 a nd 5000 ug/plate. No toxicity observed up to 5000 ug/plate; however limits of solubility exceeded at and above 167 ug/plate. Full study conducted in triplicate using 6 dosages with and without metabolic activation using rat S9 from Arochlor 1254-treated rats. Solubility exceedence noted also at and above 167 ug/plate in the full study. Positive controls used: sodium azide, 9-aminoacridine, 2-nitrofluorene, 2-anthramine. Data analyzed statistically using methodology of Snee, RD and Irr, JD, 1981. Mut. Res. 85:77-93. Used p<0.05.
Test substance	:	Purity > 97%.
Reliability	:	(1) valid without restriction Supplemental Data - Well documented study conducted according to accepted test guidance.

05.09.2002 (2)

Type	:	Cytogenetic assay
System of testing	:	Chinese Hamster Ovary Cell culture
Concentration	:	0, 50, 250, 1250, and 2500 ug/ml

Cycotoxic conc.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	OECD Guide-line 473 "Genetic Toxicology: In vitro Mammalian Cytogenetic Test"
Year	:	1994
GLP	:	yes
Test substance	:	other TS
Method	:	Preliminary cytotoxicity study conducted using 10 dosages ranging between 1 - 2500 ug/plate in DMSO. All cultures survived; dosages at and above 250 ug/ml had mitotic depressions > 50%. Full study conducted using doages of 0, 250, 1250, and 2500 ug/ml in DMSO with 5 hr treatment period with and without addition of S9. Cells were harvested 24 and 48 hr after treatment started. A second study phase was conducted where cells were exposed to 0, 50, 250, 1250 or 2500 ug/ml in the absence of S9 for 24 hr and 48 hr, at which time the cells were harvested. Duplicate cultures were run for each dosage group. Positive controls used were MNNG and DMN. Colcemid was added to each culture 2 - 3 hr prior to harvest to arrest dividing cells and metaphase slides were prepared and stained for microscopic analysis. Data from 100 metaphases (200/dose) per culture were pooled for statistical treatment using Chi-square and pairwise, 1-tailed t-tests. $p<0.05$.
Result	:	No statistically significant increases in proportion of aberrent metaphases or in the frequency of aberrations per metaphase was obsered at any level tested. DHA was concluded to be non-clastogenic.
Test substance	:	Purity > 97%.
Reliability	:	(1) valid without restriction Well documented study conducted according to accepted testing guidelines; provided as Supplemental information

06.09.2002 (4)

5.6 GENETIC TOXICITY 'IN VIVO'

Type	:	Cytogenetic assay
Species	:	rat
Sex	:	male/female
Strain	:	Sprague-Dawley
Route of admin.	:	gavage
Exposure period	:	once
Doses	:	0, 1,000, 3,000 and 10,000 mg/kg
Result	:	negative
Method	:	OECD Guide-line 475 "Genetic Toxicology: In vivo Mammalian Bone Marrow Cytogenetic Test - Chromosomal Analysis"
Year	:	1984
GLP	:	yes
Test substance	:	other TS
Method	:	Test article administered in corn oil to groups of 24 male and 24 female rats using a dosing factor of 20 ml/kg. Each animal was injected two hrs prior to scheduled sacrifice with colchicine to inhibit mitosis. Groups of 6 male and 6 female rats from each dosage group were sacrificed after 6, 12, 24 and 48 hrs after treatment. Bone marrow cells were processed according to Evans, 1977. As there was no evidence of mitotic delay observed in this study, slides from the 48 hr animals were not assessed. Kruskal-Wallis nonparametric analysis and non pairwise group comparisons were used to analyze the frequency of chromosomal aberrations detected. $p< 0.05$. Cyclophosphamide was used as a positive control.
Result	:	No statistically significant differences were observed in mean modal numbers or mean mitotic indices between treated and control groups. No mutagenic activity was observed.

mutagenic activity was observed.

Test substance	:	Purity > 97%.
Reliability	:	(1) valid without restriction Well documented study conducted according to accepted test gudelines; provided as Supplemental information.

05.09.2002 (1)

Type	:	Micronucleus assay
Species	:	mouse
Sex	:	male/female
Strain	:	CD-1
Route of admin.	:	i.p.
Exposure period	:	Single dose
Doses	:	0, 500, 1,600 and 5,000 mg/kg
Result	:	negative
Method	:	OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
Year	:	1991
GLP	:	yes
Test substance	:	other TS
Method	:	A preliminary study was run to determine toxicity: 2 males and 2 females were given 500, 1000, 2000, 3000, 4000, or 5000 mg/kg DHA by IP injection in corn oil. No deaths and limited effects were observed even at the highest level tested. Hence, the final s tudy was conducted at a maximum level of 5000 mg/kg. DHA was administered by IP injection using corn oil at rate of 10 ml/kg to groups of 5 male and 5 female mice per dosage level. A triethylenemelamine positive control group as well as a negative control group were also used. Animals were sacrificed 12, 24 and 48 hrs after treatment and slides prepared from cells obtained from femoral marrow. Stained slides were coded and analyzed for the number of PCEs with micronuclei. 1000 PCEs/animal were evaluated. The ratio of PCE:NCE/1000 cells was also calculated. Statistical treatment used a one-tail t-test. $p<0.05$.
Test substance	:	Purity > 97%
Reliability	:	(1) valid without restriction Well documented study conducted according to accepted test guidelines.
Flag	:	Critical study for SIDS endpoint

05.09.2002 (3)

5.7 CARCINOGENITY

5.8 TOXICITY TO REP RODUCTION

5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.10 OTHER RELEVANT INFORMATION

5.11 EXPERIENCE WITH HUMAN EXPOSURE

(1) Solutia Study no. HL19830210. In Vivo Bone Marrow Chromosome Study in Rats– SANTICIZER 367.

(2) Solutia Study no. PK19910403. Ames/Salmonella Plate Incorporation Assay on Test Article XA-2562.

(3) Solutia Study no. PK19910404. In Vivo Micronucleus Test of XA-2562 in Erythropoietic Cells of the Mouse Bone Marrow.

(4) Solutia Study no. PK19930370. In Vitro Chromosomal Aberration Analysis of XA-2562 in Chinese Hamster Ovary (CHO) Cells.

7.1 END POINT SUMMARY

7.2 HAZARD SUMMARY

7.3 RISK ASSESSMENT

I U C L I D

Data Set

Existing Chemical	:	ID: 103-23-1
CAS No.	:	103-23-1
EINECS Name	:	bis(2-ethylhexyl) adipate
EINECS No.	:	203-090-1
TSCA Name	:	Hexanedioic acid, bis(2-ethylhexyl) ester
Molecular Formula	:	C22H42O4

Producer Related Part

Company	:	Solutia Inc.
Creation date	:	04.09.2002

Substance Related Part

Company	:	Solutia Inc.
Creation date	:	04.09.2002
Memo	:	
Printing date	:	25.10.2002
Revision date	:	
Date of last Update	:	05.09.2002
Number of Pages	:	10
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 OECD AND COMPANY INFORMATION

1.0.2 LOCATION OF PRODUCTION SITE

1.0.3 IDENTITY OF RECIPIENTS

1.1 GENERAL SUBSTANCE INFORMATION

1.1.0 DETAILS ON TEMPLATE

1.1.1 SPECTRA

1.2 SYNONYMS

1.3 IMPURITIES

1.4 ADDITIVES

1.5 QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.7 USE PATTERN

1.7.1 TECHNOLOGY PRODUCTION/USE

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.9 SOURCE OF EXPOSURE

1.10.1 RECOMMENDATIONS/PRECAUTIONARY MEASURES

1.10.2 EMERGENCY MEASURES

1.11 PACKAGING

1.12 POSSIB. OF RENDERING SUBST. HARMLESS

1.13 STATEMENTS CONCERNING WASTE

1.14.1 WATER POLLUTION

1.14.2 MAJOR ACCIDENT HAZARDS

1.14.3 AIR POLLUTION

1.15 ADDITIONAL REMARKS

1.16 LAST LITERATURE SEARCH

1.17 REVIEWS

1.18 LISTINGS E.G. CHEMICAL INVENTORIES

2.1 MELTING POINT

2.2 BOILING POINT

2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

2.5 PARTITION COEFFICIENT

2.6.1 WATER SOLUBILITY

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

3.1.2 STABILITY IN WATER

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.1.1 ACUTE ORAL TOXICITY

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test
System of testing	:	Plate incorporation assay with TA1535, TA1537, TA1538, TA98, & TA100
Concentration	:	0.15, 0.47, 1.5, 4.74, 15,8, 47.4, and 150 ul/plate
Cycotoxic conc.	:	no cytotoxicity up to 150 ul/plate in either preliminary or final study
Metabolic activation	:	with and without
Result	:	negative
Method	:	OECD Guide-line 471 "Genetic Toxicology: Salmonella thyphimurium Reverse Mutation Assay"
Year	:	1983
GLP	:	yes
Test substance	:	no data
Method	:	Agar incorporation method consistent with OECD and EPA guidance. Three plates per dose used. In addition to 7 concentration of test article, positive (sodium azide, 9-aminoacridine, 2 -nitrofluorene, and 2-antramine) controls, a negative control and a solvent control were tested. S9 mix was commercially available from rats treated with Arochlor 1254. Test material was dissolved in Dimethyl Formamide (50 ul/plate). A preliminary cytotoxicity study was performed with TA100 using 14 graded doses ranging between 0.02 and 150 ul/plate. No cytotoxicty was observed up to the highest level tested.
Reliability	:	(1) valid without restriction Well conducted and documented study which followed accepted testing guidelines; provided as Supplemental information.

05.09.2002 (1)

5.6 GENETIC TOXICITY 'IN VIVO'

Type	:	Micronucleus assay
Species	:	mouse
Sex	:	male/female
Strain	:	B6C3F1
Route of admin.	:	i.p.
Exposure period	:	One group administered single dose; second group administered 2 doses, 24 hr apart
Doses	:	Group 1 - 5,000 mg/kg; Group 2 - Total of 10,000 mg/kg (2 doses each of 5,000 mg/kg)
Result	:	negative
Method	:	OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
Year	:	1982
GLP	:	yes
Test substance	:	no data
Method	:	Used 6 male and 6 female B6C3F1 mice per dose group, which included mice receiving 5,000 mg/kg test material either once, or two times over a 24 hr period; both a positive (triethylenemelamine) and negative control also tested. A preliminary range-find study was conducted up to 5,000 mg/kg producing no deaths or toxicologic effects. Marrow was excised from the tibia of each animal and processed; slides from 4 males and 4 females per group were randomly selected for scoring of 1000 PCEs /animal.Students-t test was applied to data for males and females separately and pooled. p<0.05 used throughout.
Result	:	No statistically significant differences were observed between treated and control animals in the per cent micronucleated PCEs identified; no mitotic depression was observed in the treated groups.
Reliability	:	(1) valid without restriction Well conducted and documented study which followed accepted testing guidelines.
Flag	:	Critical study for SIDS endpoint

05.09.2002 (2)

5.7 CARCINOGENITY

5.8 TOXICITY TO REPRODUCTION

5.9 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.10 OTHER RELEVANT INFORMATION

5.11 EXPERIENCE WITH HUMAN EXPOSURE

(1) Litton Bionetics. 1982. Lab Project No. LBI 20988 conducted for CMA, Washington, DC.(Solutia study no. BO1983X141).

(2) Litton Bionetics. 1982. Lab Project No. LBI 20996 conducted for CMA, Washington, DC.(Solutia study no. BO1983X138).

7.1 END POINT SUMMARY

7.2 HAZARD SUMMARY

7.3 RISK ASSESSMENT